

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No.: PT/DISALVO

In re Application of:)	
Francesco DiSalvo et al.)	
Appl. No.: 10/726,100)	Examiner: Pete Vrettakos
Filed: December 2, 2003)	Group Art Unit: 3739
For: SILVER ALLOYS FOR USE IN MEDICAL, SURGICAL AND MICROSURGICAL INSTRUMENTS AND PROCESS FOR PRODUCING THE ALLOYS)	

DECLARATION OF DR. JAMES T. GOODRICH UNDER RULE 132

James T. Goodrich hereby deposes and states:

1. I am a physician specializing in pediatric neurological surgery and a professor of Clinical Neurological Surgery, Pediatrics at the Albert Einstein College of Medicine in New York City. I received my MD degree from Columbia University College of Physicians and Surgeons in 1980 in New York City. Internship and residency training from 1980 to 1986 I completed at the Presbyterian Hospital in New York City and the New York Neurological Institute also in New York City. I hold MA and PhD degrees from the Graduate School of Arts and Sciences of Columbia University. I am presently the director of the Division of Pediatric Neurosurgery and hold the academic title of Professor of Clinical Neurological Surgery, Pediatrics, Plastic and Reconstructive Surgery at the Albert Einstein

College of Medicine. I also hold the rank of Professor Contralto of Neurological Surgery at the University of Palermo in Palermo, Italy.

2. My present position as Director of the Division of Pediatric Neurosurgery at Albert Einstein Medical College I have held since 1986. The specialty interests of the center and especially my interest is in pediatric neurosurgery which includes craniofacial disorders and their surgical correction, pediatric brain and spine disorders, hydrocephalus, spinal bifida/dysraphism including myelomeningocele, tethered spinal cord, lipomyelomeningocele, Chiari malformations plus traumatic and tumor disorders involving the peripheral nervous system such as brachial plexus injury both from birth and traumatic origin as well as blunt and sharp traumatic injuries of peripheral nerves. In my capacity as a surgeon I carry out surgical procedures on these syndromes on a daily/weekly basis.

3. As a surgeon I have been peer reviewed and voted nationally as one of the best physicians in New York in my specialty. I am also a peer reviewer for a number of neurosurgical journals and I am Section Editor for 'Classics in Pediatric Surgery' for the journal 'Child's Nervous System'. To date I have published approximately 230 papers, articles and editorial comments. I have authored the books as listed and attached hereto as Exhibit A.

4. I make this declaration in support of U.S. Patent application No. 10/10/726,100 entitled "SILVER ALLOYS FOR USE IN MEDICAL, SURGICAL AND MICROSURGICAL INSTRUMENTS, AND PROCESS FOR PRODUCING THE ALLOYS" and covering inventions relating to an alloy and the use of the alloy for surgical instruments (the Patent Application) naming as inventors Mr. Francesco DiSalvo and Dr. Matteo Tutino and that I know to be currently pending in the United States Patent and Trademark Office. I am very familiar with the instruments made from the alloy covered by the invention.

5. One of the inventors, Dr. Tutino and I have a close professional relationship. I first met Dr. Tutino in 1994 when he was a resident fellow at University of Birmingham, Alabama. Since 1996 we have been collaborating especially in surgical procedures. My professional relationship with Dr. Tutino started in 1998/99 when Dr. Tutino received training at Montefiore Medical Center in craniofacial surgery under my supervision from February 1999 to July 1999. In the course of our professional collaboration I have become closely familiar with the development of the alloy of which Dr. Tutino is a co-inventor and which is for use in surgical instruments that are the subject of the Patent application.

6. In the course of my surgical carrier as a neurosurgeon especially in the field of pediatrics, I operate on microstructures in the brain. Our operating rooms at the Medical College are equipped with the latest technology including 3-D guided frameless imaging systems which allow me to freely work on complex lesions of

the brain and spinal cord. Brain surgery not only requires very delicate operating techniques but one of the persistent problems is the danger of tissue damage which can occur during these delicate surgical procedures. Our state of the art facility has markedly enhanced my ability to remove complex tumors and other pathologies with reduced morbidity. Regardless of this technology, tissue damage can occur through the simplest of hand instrumentation used in cutting, excising or just holding biological tissue. When preparing the operating field, structures in the brain have to be delicately moved in order to prepare for excision of a pathological growth. In the course of such excision the use of suitable surgical hand instrumentation plays a vital role. The particular problem in a surgical field of biological tissue is to keep any type of interaction of the biological tissue and the hand instrumentation at the most neutral level. An example is in avoiding the generation of tissue resistance and thus heat generation which can cause tissue damage and scarring.

7. Surgeons in general are always aware of the danger that such tissue damage can be generated with hand instrumentation and I am therefore always looking for new instruments that can be helpful in overcoming the problems of tissue damage.

8. In June 2003, Dr. Tutino introduced me to a specific electrode made from an alloy he and his co-inventor had developed. The instrument, I was told, was made from an alloy unlike other alloys normally used for making surgical instruments such as for example forceps, electrodes, scalpels and such. Dr. Tutino

explained to me that the special features of the surgical instruments made from this alloy was the fact that usage of these instruments reduced the scarring of biological tissue. It was explained to me that through the specific metal matrix present in the alloy electron, transfer was kept to a minimum and thus avoided an instrument that develops a high resistance and thus the generation of unacceptable heat.

9. Beginning in 2004, I started using these surgical instruments made from this new alloy and was impressed with the excellent results in that tissue damage via thermal damage was markedly reduced. In 2003-2004 I was lead surgeon of a neurosurgical team of nearly 30 surgeons who conducted a craniopagus surgery on the Philippine conjoined twins that were joined at the head. The surgeries, in which the surgical instrumentation from the new alloy was used, were very successful and both twins have survived with no complications.

10. I believe that the surgical instrumentation made from the new alloy is a significant improvement over the standard instrumentation in that it is definitely improved and has superior performance in reducing tissue damage. I believe that the instrumentation using this new alloy fulfills a long felt need for improved performance and reduction in tissue damage from thermal currents. I also understand that since its introduction into the market, there has been a significant demand for the surgical instruments made from the alloy. This has been reflected in demand in the market place and sales.

10. As I am familiar with the content of the Patent Application including the rejection by the Examiner based on an electrode for external use. I am specifically directing my statements to Patent No.: 4,375,219 to Schmid the Examiner cited, which I refer to hereinafter as the "Schmid" reference.

11. The following is my evaluation and my further substantive statements regarding the invention in view of the Schmid reference. Schmid discloses an electrode used for EKG measurement. EKG measurement is carried out on the surface of the skin. The electrode as shown and taught by the Schmid reference clearly is an electrode for topical application only, namely for measuring heart activity. As a surgeon, I am surprised that the Examiner stated that the Patent Office can take the position that such electrode is implantable. In my opinion, I can safely say that an electrode such as developed by Schmid would never be used for implantation into a body, nor is it the type of surgical electrode that would be used in surgical procedures. Thus, the electrode described by Schmid is not usable as a surgical electrode and as such does not represent a "surgical instrument". I also particularly noted that the alloy from which the Schmid electrode is made has a different composition; it has a much larger percentage of germanium than the alloy from which the surgical instruments which are the subject here are made. I am aware that the range of germanium content is critical to the favorable characteristics of the alloy for use in direct contact with biological muscle or brain tissue.

12. I am very much aware of the interaction of internal body tissue with a surgical instrument made from this new alloy. I have also noted superior surgical results in tissue interaction as compared to the conventional instruments. This result is due to the low resistance created in tissue interaction and also due to the emission of far infrared radiation. I know from my discussions with Dr. Tutino that the favorable characteristics of the surgical instruments are in part due to the particular content range of germanium as well as the application of a dopant in the metal alloy. In my long-term surgical experience no other surgical instruments were comparable in results to those that I have tried in surgery made from this alloy.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Date: 12/5/01


Dr. James T. Goodrich

EXHIBIT A

Books

Goodrich, J.T., Post, K.D. and Argamaso, R. (1991) *Plastic Techniques for Neurosurgeons*. Thieme Medical Publishers, Inc., New York.

Clinical Neurosurgery. Proceedings of the Congress of Neurological Surgeons - Chicago 1993.
Associate Editor

Clinical Neurosurgery. Proceedings of the Congress of Neurological Surgeons - Vancouver, BC, 1994. Associate Editor

Clinical Neurosurgery. Proceedings of the Congress of Neurological Surgeons - Chicago 1995.
Associate Editor

Goodrich, J.T. and Hall, C.D. (1995) *Craniofacial Anomalies: Growth and Development from a Surgical Perspective* Thieme Medical Publishers, Inc., New York.

Goodrich, JT (1996) *Video Surgical Workshop of Craniofacial Surgery and Transfacial Approaches to the Skull Base*. Medical Video Productions, St Louis, MO

Goodrich JT (1997) *Techniques in Neurosurgery - Craniosynostosis/Craniofacial Surgery*. Lippincott-Raven Publ. Philadelphia, PA.

Keating, R.F., Packer R. and Goodrich, J.T. (2001) *Tumors of the Pediatric Nervous System. Current Diagnosis and Management and Future Perspectives*. Thieme Medical Publishers, Inc. New York.

Goodrich, J.T., Staffenberg D. (2004) *Plastic Techniques for Neurosurgeons - Second Edition*. Thieme Medical Publishers, Inc., New York.

Chico Ponce de Leon, F, Sierra Eduardo Castro, Goodrich JT. *Techniques of Cranial Surgery in Mexico City XVI Century*. Difusion & Tecnologia, Mexico City 2005

Goodrich J.T. (Editor) *Operative Neurosurgical Atlas. Second Edition*. Thieme Medical Publishers, Inc. New York. In press, due 2006.